Axio BioPharma

AI in BIOMANUFACTURING

How operating models, digital twins, and federated intelligence are reshaping the biologics manufacturing ecosystem

2026-2029 OUTLOOK

April 2026

Credits & Disclaimer

Authorship

This report was authored by Dave Watrous, Chief Commercial Officer at Axio BioPharma. His work focuses on operating models, ecosystem strategy, and federated intelligence in biomanufacturing. Contributions were provided by Justin Byers, Founder & CEO, and Brian Staats, Co-founder & CTO.

It reflects Axio BioPharma's perspective on the evolution of AI, operating models, and digital infrastructure across the biologics manufacturing ecosystem.

Acknowledgments

We thank colleagues and collaborators across sponsors, CDMOs, equipment vendors, and regulators who provided discussions, feedback, and context that informed this report.

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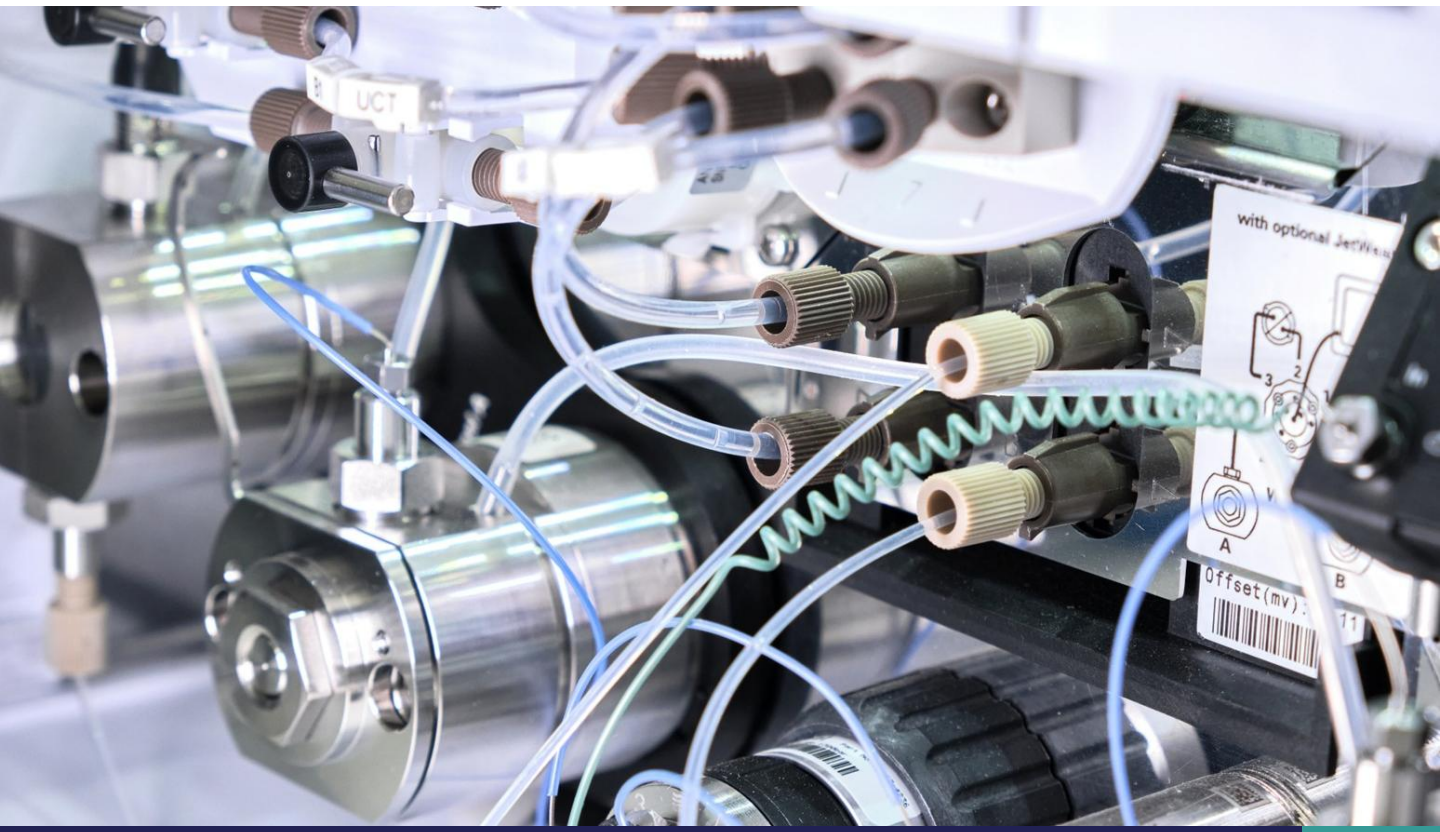

AGENDA

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How to Read This Report

For Executives

Focus on the Executive Summary (pages 5–7), the maturity and ecosystem framework (pages 12–15), and the "What to Do Now" actions (page 24). These pages connect economics, regulatory expectations, and practical operating-model implications for scaling AI in biologics manufacturing.[1–9]

For Digital, Operations, and Quality Leaders

Read Part I to understand adoption realities and constraints (pages 9–10), then Part II to anchor readiness and governance (pages 12–15). Part III translates this into operating models, use cases, and organizational requirements (pages 17–21), aligned with regulatory and GxP guidance for AI-enabled systems.[3–8]

What This Report Is (and Is Not)

This is a biologics and CDMO centric synthesis of AI readiness, adoption patterns, governance expectations, and implementation playbooks.[1–13] It is not a vendor procurement guide, legal advice, or an exhaustive technical manual for model development.[3–7]

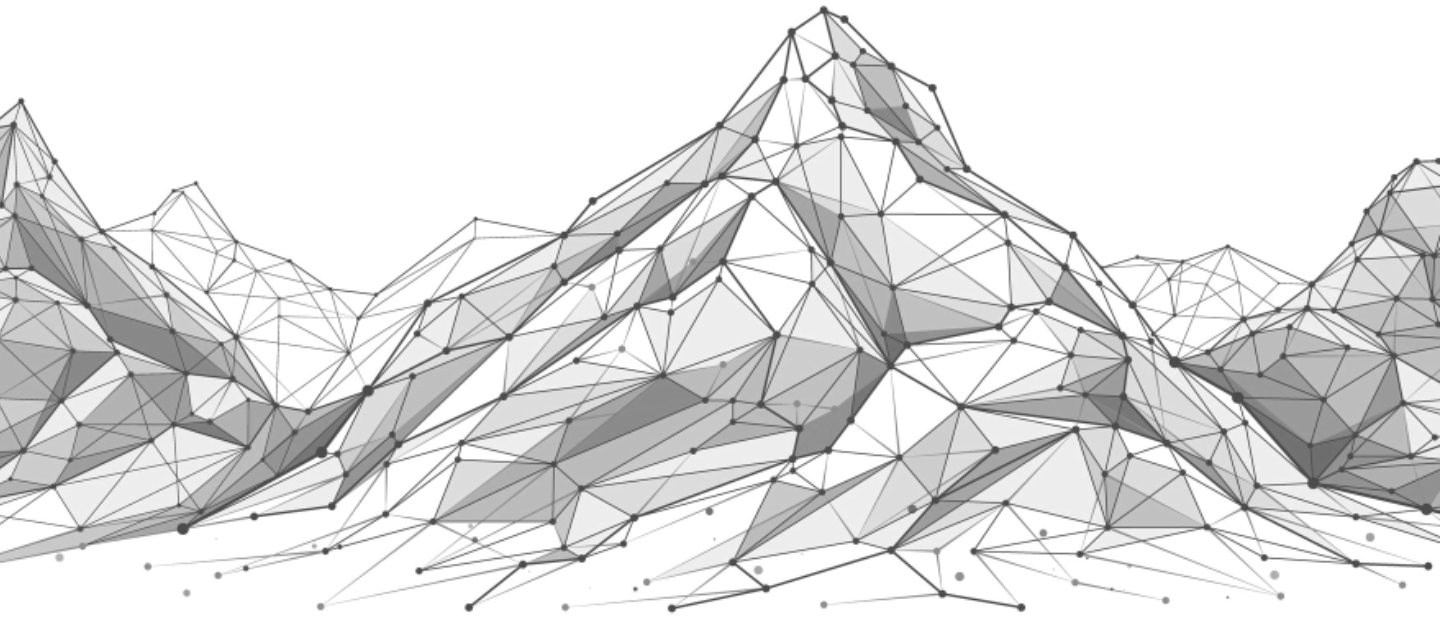
EXECUTIVE SUMMARY

As of early 2026, biologics are central to global pipelines, but biologics manufacturing remains structurally constrained. Capacity is tight, cycle times are long, and outsourcing to CDMOs continues to increase - amplifying complexity and dependency on external networks.[1] At the same time, AI adoption in life sciences has accelerated, with many organizations implementing AI ahead of mature governance and compliance practices.[2]

Between 2023 and 2025, regulators and standard-setters moved from broad AI awareness to concrete expectations. EMA's reflection paper, EFPIA positions, FDA's AI draft guidance, the draft EU GMP Annex 22, and ISPE's GAMP® Guide for AI collectively define what "acceptable" AI looks like in GxP environments and how AI-enabled computerized systems should be managed across their lifecycle.[3–7]

Despite progress, AI in biologics manufacturing remains uneven. Most deployments are concentrated in process development analytics, monitoring, and advisory use cases, while digital twins and advanced control remain largely in pilots.[10–13] The persistent barrier is less algorithmic capability and more digital maturity, data integration, governance, and multi-party operating models especially across sponsor–CDMO relationships.[8,9]

This report defines the Biomanufacturing AI Maturity Index (BAMI) that overlays DPMM and DISCO and introduces a federated ecosystem model that reflects how biologics manufacturing operates today – across sponsors, CDMOs, vendors, and regulators.[8,9,12] It then lays out an implementation playbook and a set of predictions for 2026 – 2029.



Key **Takeaways**

01 **AI is gated by digital and integration readiness.**
Most biologics plants operate at mid range digital maturity; without robust data integration and standardized sponsor–CDMO digital interfaces, AI struggles to scale beyond local pilots.[8,9]

02 **Regulatory expectations are converging.**
EMA, EFPIA, FDA, the draft EU GMP Annex 22, and ISPE GAMP AI now form a coherent expectations and implementation stack for AI in GxP environments.[3–7]

03 **BAMI adds an AI lens over DPMM and DISCO.**
BAMI (Biomanufacturing AI Maturity Index) defines six levels (0-5) of AI capability, from siloed/manual to AI native biologics manufacturing, focusing on data fitness, model lifecycle governance, portability, and inspection readiness.[8,9]

04 **The ecosystem is federated by design.**
Biologics manufacturing is distributed across sponsors, CDMOs, and vendors; cross site learning will rely on federated or privacy preserving approaches rather than centralized pooling. [12,13]

05 **Digital twins and AI will become standard in new builds.**
Digital twins of key unit operations, combined with PAT and analytics, are expected to become standard design features in new or heavily upgraded biologics facilities, especially among leading CDMOs.[10,12,13]

06 **Workforce & operating models are the binding constraint.**
Skills gaps, unclear ownership of model lifecycles, and misaligned incentives increasingly determine whether AI moves from pilots to durable advantage.[2,14,15,17]

Executive Summary
at a Glance

The Core Stack

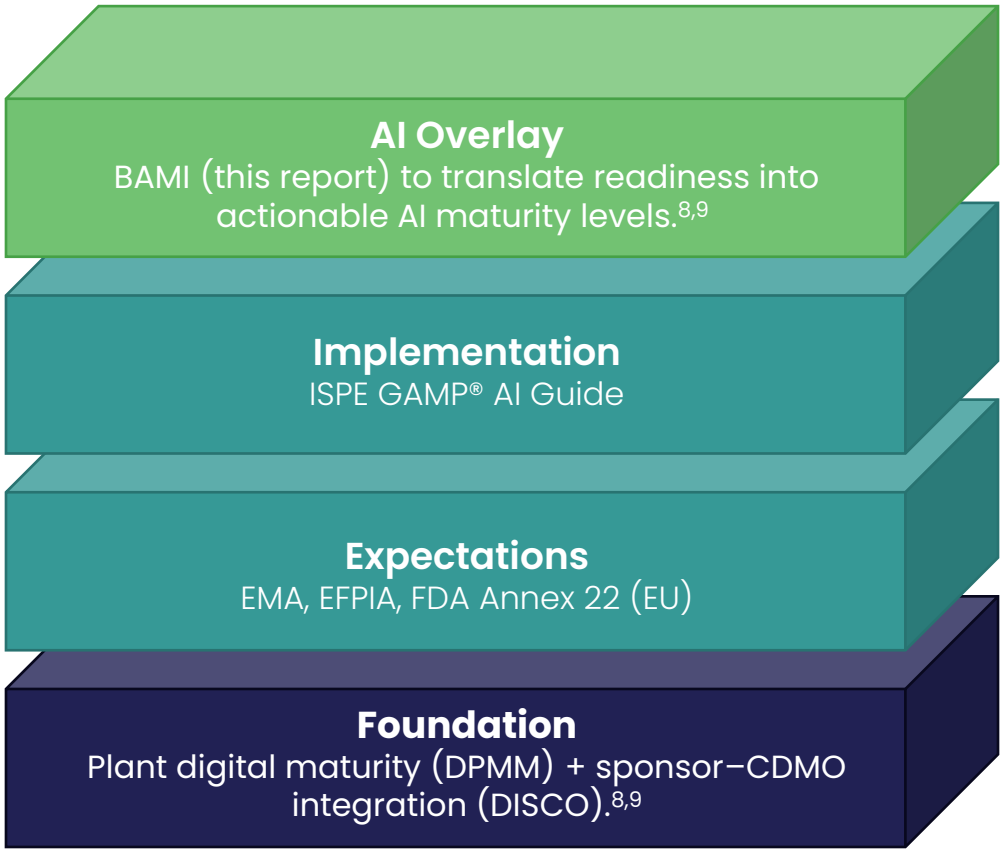


Figure 1. The Core Stack for AI-enabled biomanufacturing.
Digital maturity and sponsor–CDMO integration form the foundation, regulatory guidance defines expectations, GAMP® provides the implementation framework, and BAMI overlays these layers to translate readiness into practical AI maturity levels. In practice, scaling across this stack requires systems that can operationalize model lifecycle management, cross-site learning, and governed data exchange across organizational boundaries.

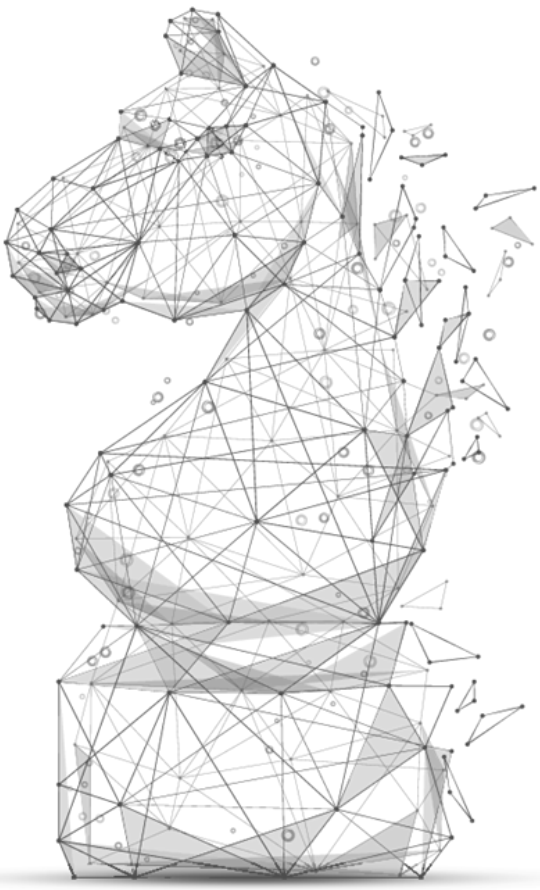
Three core questions for leaders

- Where is AI economically meaningful (yield, cycle time, deviations, release lead time)?[1,10]
- How mature are our plants and partnerships across DPMM, DISCO, and BAMI?[8,9]
- What is our 3-5 year roadmap for digital twins and federated learning under a defensible governance model?[6,7,12]

Part I

Context

Biologics demand, CDMO dependency, and the state of **AI adoption**



This section sets the macro context for biologics manufacturing and summarizes where AI is being applied today, distinguishing scaled deployments from pilots and aspirational narratives.[1,2,10,11]

Macro Trends in Biologics Manufacturing

Industry survey data indicate that biologics manufacturing demand continues to grow and that external capacity remains central to meeting clinical and commercial needs, especially for platform modalities such as monoclonal antibodies.[1] As outsourcing expands, tech transfer volume and complexity increase, making consistent execution across sites and organizations a primary performance constraint.[1]

This operating reality changes how digital and AI capabilities must be designed: they must function across organizational boundaries, accommodate heterogeneous systems, and support collaboration among sponsors, CDMOs, and vendors; rather than assuming a single integrated enterprise.[1,9]

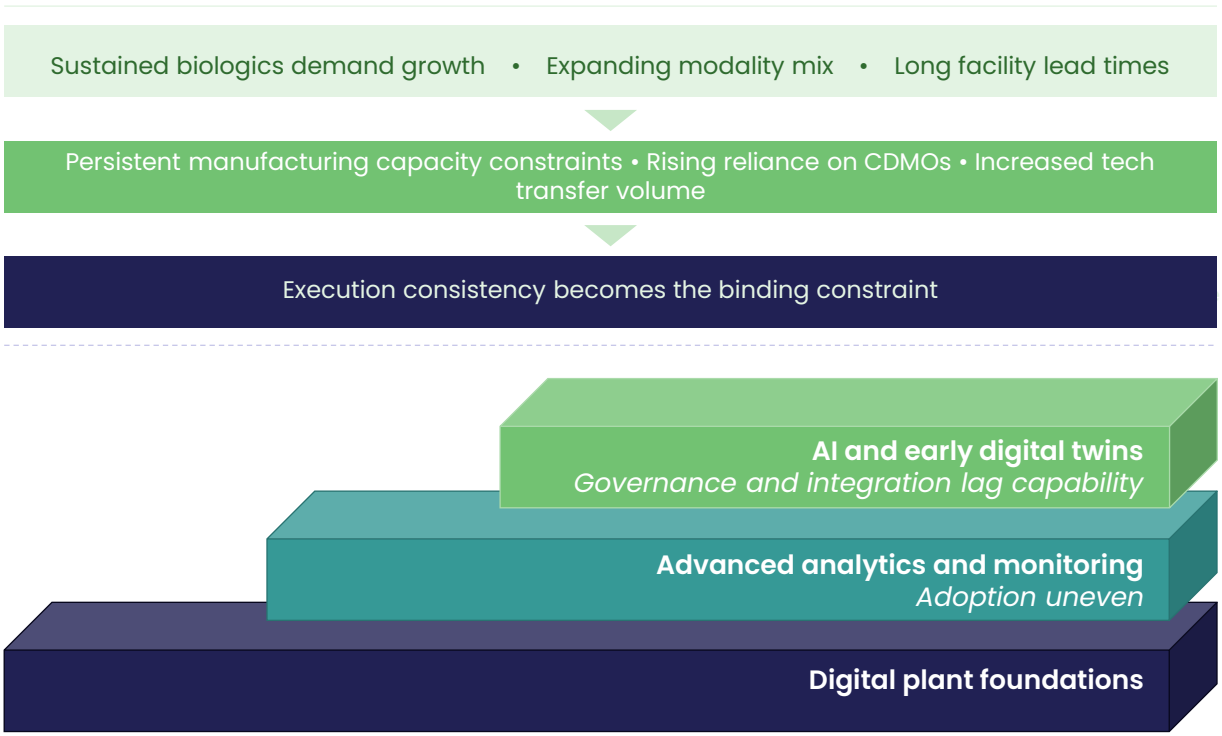


Figure 2. Macro context shaping AI adoption in biologics manufacturing
Sustained demand growth and expanding outsourcing place pressure on a capacity-constrained manufacturing base. As execution complexity increases across sponsors and CDMOs, digital foundations, analytics, and AI emerge as necessary enablers—though their impact remains gated by integration maturity and governance.

State of AI Adoption in Biologics Manufacturing

Across life sciences, AI adoption has accelerated; benchmarking indicates many organizations have implemented AI recently, while governance, policy, and audit maturity lags adoption.[2] In bioprocessing and biomanufacturing, technical literature supports the emergence of high value applications in process modeling and optimization, soft sensing and multivariate monitoring, anomaly detection, and early digital twin implementations.[10,11]

However, the gap between pilots and scaled impact remains a defining feature. Organizations frequently encounter friction from data fragmentation, inconsistent context/metadata, limited interoperability, and insufficient lifecycle governance for AI enabled systems used in regulated decisions.[7,8]

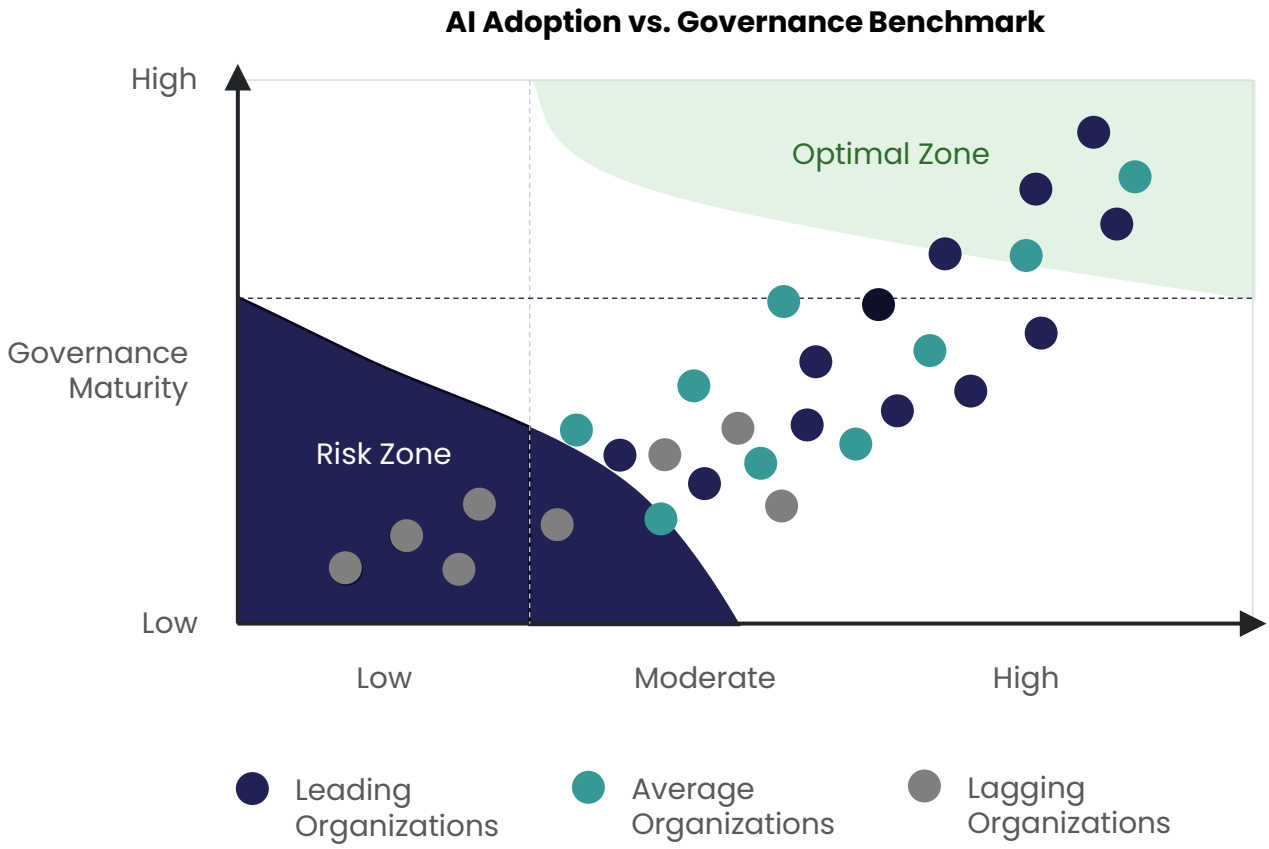
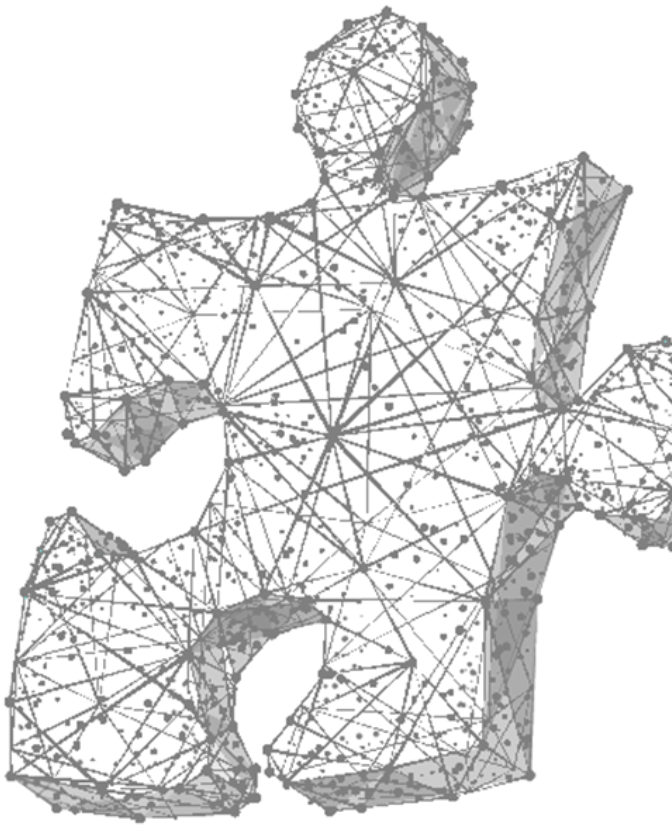


Figure 3. AI adoption versus governance maturity
Simplified and adapted from Arnold & Porter (2024); illustrative framework highlighting relative positioning rather than measured performance. This framework is intended to support strategic discussion and does not represent a formal risk or compliance assessment.

Part II –

Maturity & Ecosystem

Digital foundations, AI maturity, and **federated networks**



This section connects plant maturity (DPMM), sponsor–CDMO integration (DISCO), and the evolving regulatory/GxP guidance stack. It introduces BAMI and a federated ecosystem model as practical tools for planning AI at scale.[3–9,12]

Digital & Regulatory Foundations

BioPhorum's Digital Plant Maturity Model (DPMM) provides a structured approach to assessing plant digital maturity from paper-based operations to self optimizing plants integrated into value chains.[8] The DISCO Playbook extends maturity thinking across organizations by defining how sponsors and contract organizations can structure digital collaboration, data sharing, and implementation roadmaps.[9]

Overlaying these are evolving regulatory expectations. EMA's reflection paper, EFPIA industry positions, FDA's AI draft guidance, and the EU's draft Annex 22 collectively define expectations for data fitness, transparency, performance monitoring, and change management for AI systems that support regulated decisions.[3–6] ISPE's GAMP AI guide translates these expectations into a practical lifecycle approach for AI-enabled computerized systems in GxP environments.[7]

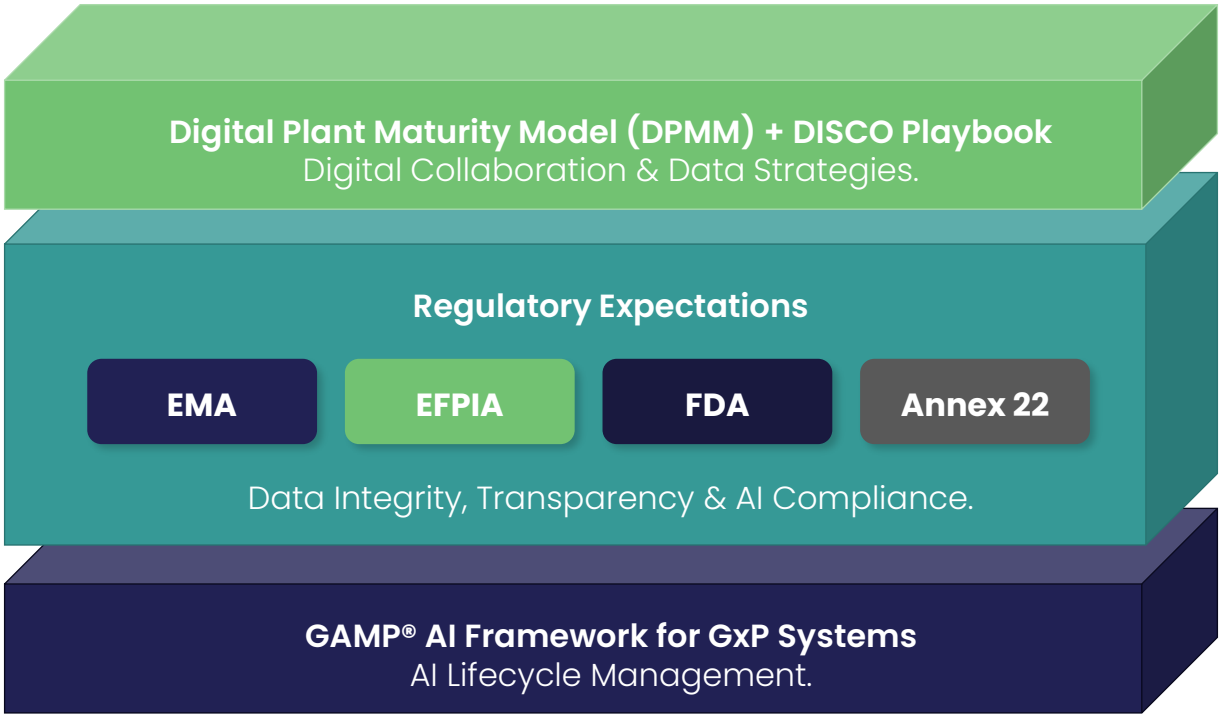


Figure 4. Governance layers enabling AI in regulated biomanufacturing.
Digital maturity frameworks (DPMM and DISCO) define the operational and collaboration foundations, regulatory guidance sets expectations for trustworthy AI use, and GAMP AI provides the lifecycle framework for implementing and maintaining AI systems in GxP environments.

Biomanufacturing AI Maturity Index (BAMI)

BAMI is a six-level (0–5) maturity model that defines how AI capabilities evolve in biologics manufacturing, from siloed, reactive operations to autonomous, networked systems. It integrates plant digital maturity with sponsor–CDMO coordination to assess what organizations can realistically deploy today and what is required to scale [8,9].

Maturity is determined across five dimensions that collectively define whether AI can be governed, scaled, and transferred across sites:

1. Data foundation & cross-system interoperability (context, metadata, integration) [8]
2. Model lifecycle governance & validation (monitoring, change control) [6,7]
3. Process portability & model-driven tech transfer (model & artifact portability)
4. Operational integration (MES/LIMS/historian + decision workflows) [8]
5. Regulatory alignment & inspection readiness [3–7]

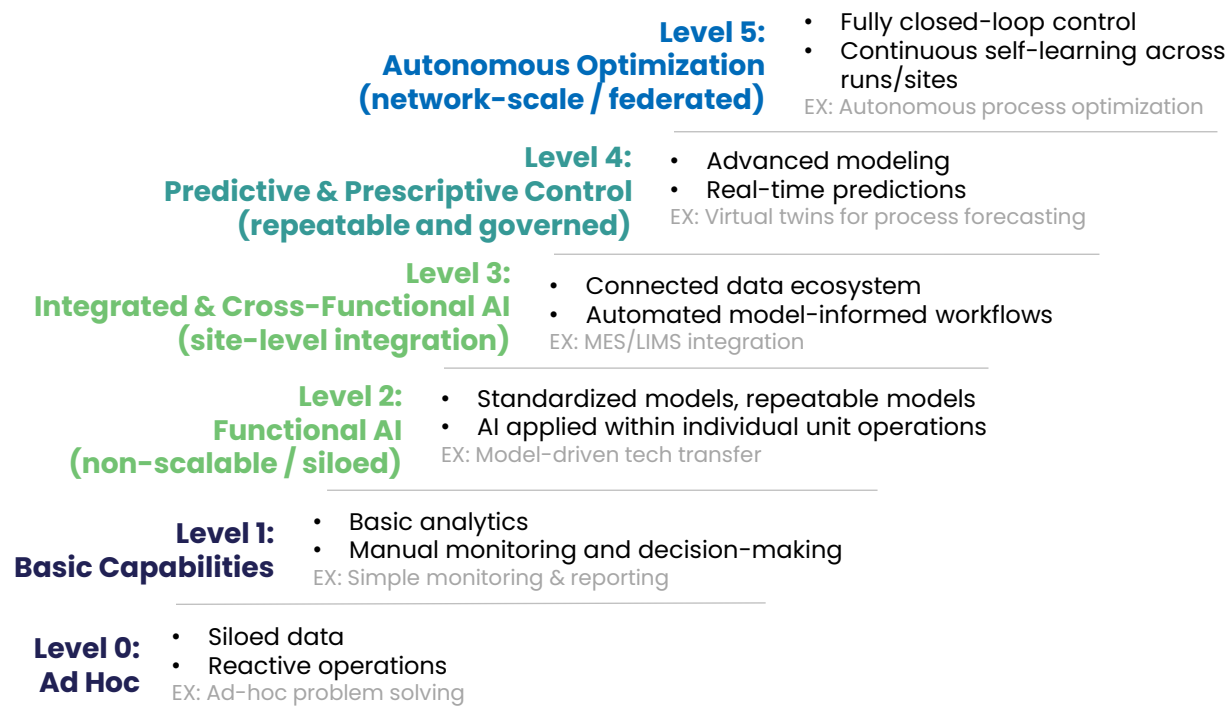


Figure 5. Biomanufacturing AI Maturity Index (BAMI)

Six-level (0–5) framework showing the evolution from ad hoc data use to autonomous, AI-driven biologics manufacturing, with increasing capability in data interoperability, governance, process portability, operations, and regulatory alignment. Most organizations operate between Levels 1 and 3, where AI remains fragmented and difficult to scale. Advancing requires not just better models, but stronger data foundations, integration, and governance. 7,8,10,11

BAMI - DPMM Crosswalk

AI capability in manufacturing is fundamentally limited by digital plant maturity:

1. DPMM Levels 1-2 typically limit organizations to BAMI Levels 0-2 due to fragmented systems and lack of contextualized data.[8]
2. DPMM Levels 3-4 can support BAMI Levels 3–4 by enabling cross-functional data integration, soft sensors, and operational predictive models.[8,10,11]
3. DPMM Level 5 enables BAMI Level 5, including federated learning, cross-site model reuse, and digital twin–driven operations.[8,12]

This crosswalk makes clear why most AI initiatives stall: advanced models are consistently deployed on insufficient digital and integration foundation. [8]

DPMM \ BAMI	Level 0 No AI Capability	BAMI 1 Basic AI Capabilities	BAMI 2 Functional AI (within silo)	BAMI 3 Cross-functional AI (within site)	BAMI 4 Predictive Models	BAMI 5 Federated
1: Pre-digital Plant	✓	/	×	×	×	×
2: Digital Silos	✓	✓	/	/	×	×
3: Connected Plant	✓	✓	✓	/	/	×
4: Predictive Plant	✓	✓	✓	✓	/	/
5: Adaptive Plant	✓	✓	✓	✓	✓	✓

✓ = enabled / = partial / emerging (non-scalable) × = not present

Figure 6. Relationship between digital plant maturity and AI capability in biomanufacturing.

This matrix maps Digital Plant Maturity Model (DPMM) levels (rows) to Biomanufacturing AI Maturity Index (BAMI) levels (columns), illustrating typical real-world combinations. Early-stage plants support limited AI use, while higher levels of digital integration enable predictive models, cross-functional analytics, and ultimately federated learning and digital twin–driven operations. AI maturity in regulated manufacturing is constrained by data integration, system interoperability, and governance.

Federated Biologics Network

Biomanufacturing is intrinsically multi-party, spanning sponsors, CDMOs, equipment vendors, digital platforms, and regulators. In this environment, centralized data strategies are structurally constrained by IP, confidentiality, and competitive boundaries.[12,13]

As a result, a federated model is not optional—it is required. Sensitive data must remain local, while learning is enabled through the exchange of standardized artifacts such as features, models, and process-as-code under shared governance.[12,13]

Emerging platforms are beginning to operationalize this model by enabling governed exchange of models and process intelligence without requiring centralization of raw data. [12,13]

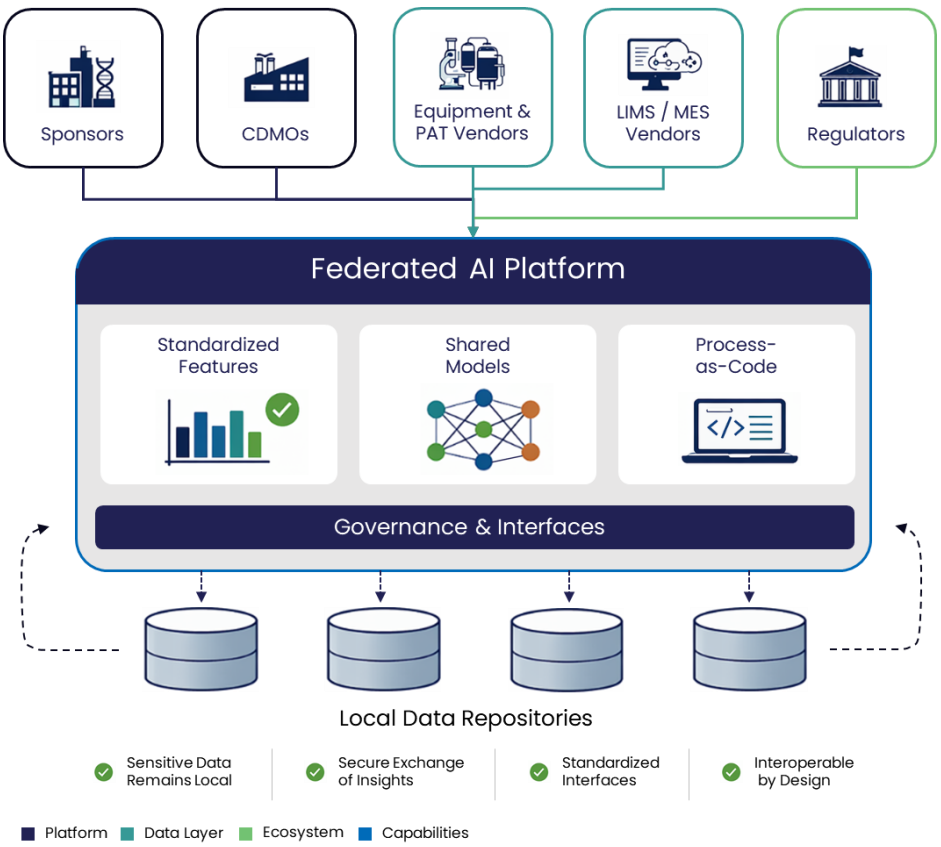
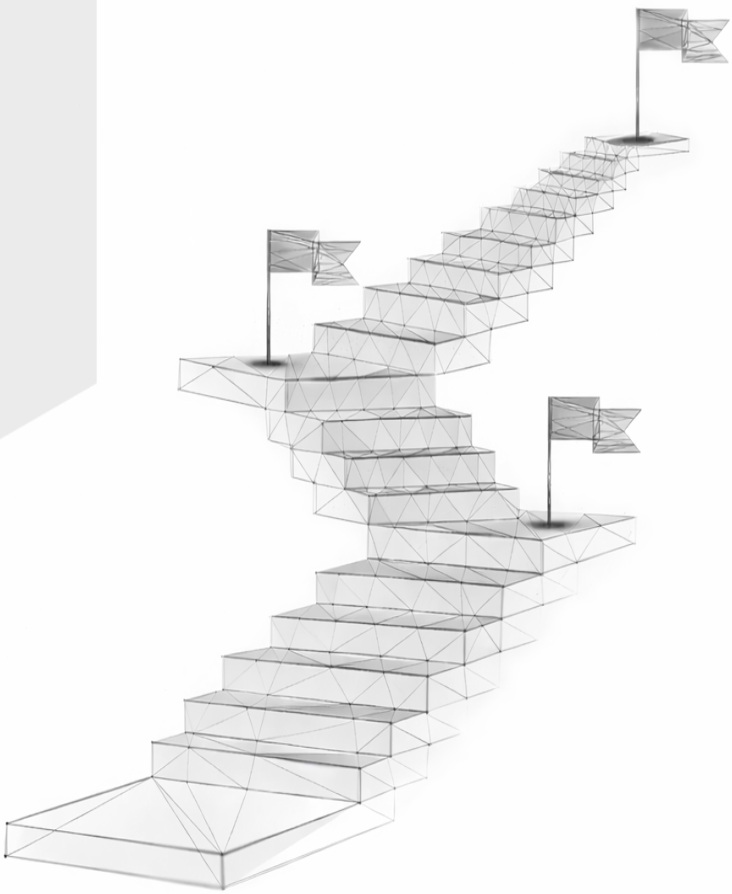


Figure 7. Federated AI model for multi-party biologics manufacturing.
Sensitive operational data remains within each organization while standardized artifacts such as features, models, and process-as-code are exchanged through governed interfaces to enable cross-site learning across sponsors, CDMOs, technology vendors, and regulators.

Part III –

Operating Models & Playbook

From use cases to a **governed roadmap**

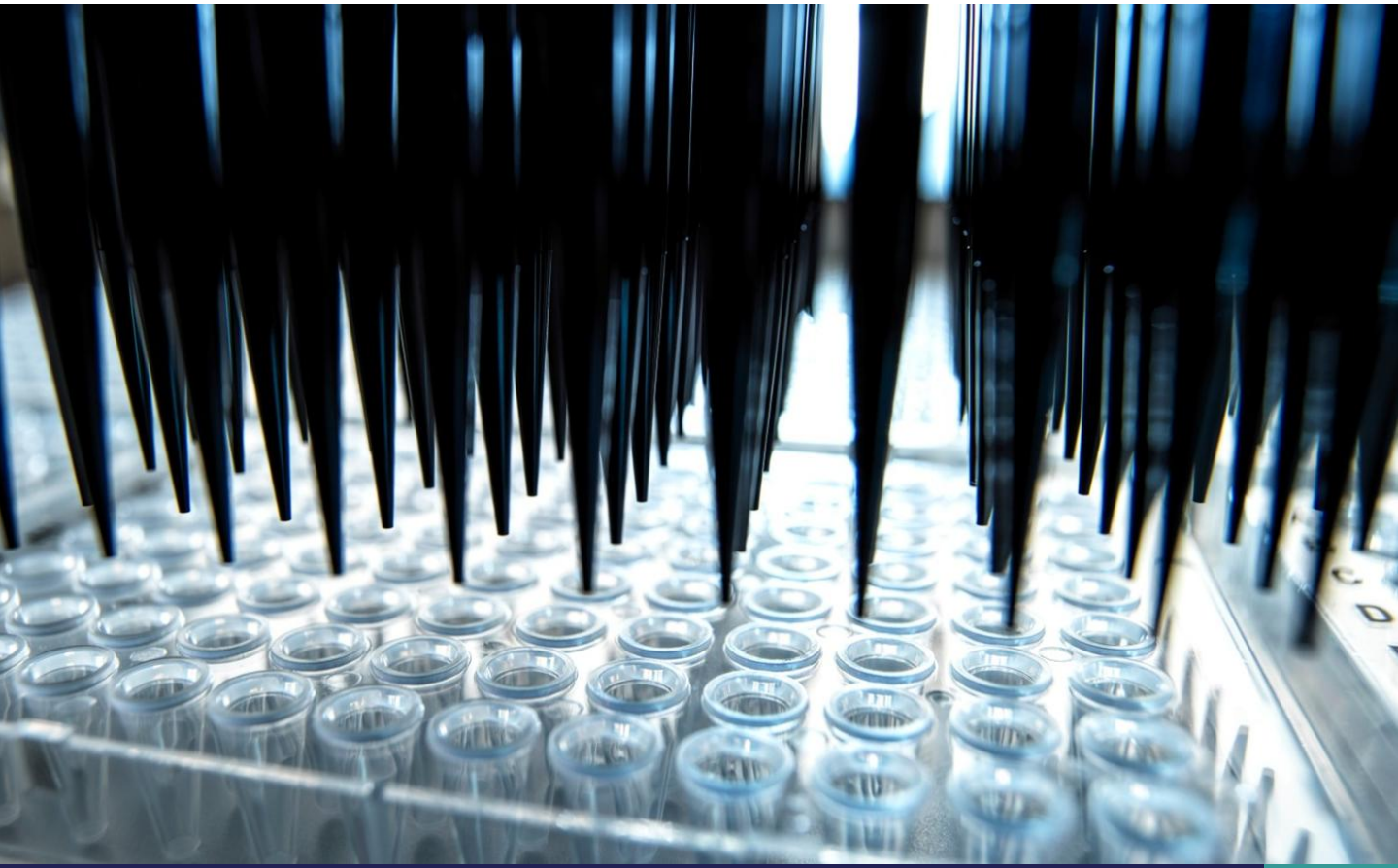


This section describes where AI is applied across process development, tech transfer, manufacturing, and quality; clarifies CDMO operating archetypes; identifies structural stall points; and provides a phased playbook aligned with the emerging governance stack.[3–13]

Process Development and Tech Transfer

In process development, AI and advanced analytics are used to accelerate understanding and optimization: algorithm assisted DoE, response surface modeling, media/feed optimization, and early unit operation digital twins [10,11] These approaches reduce experimental burden and can improve speed to robust process understanding when supported by high quality data and appropriate modeling discipline.[10,11]

In tech transfer, the operating challenge is portability and comparability across sites and partners. Model assisted comparability and process as code concepts can support better anticipation of scale and equipment effects, reducing friction in PPQ and ramp up.[10–12] Where models inform regulated decisions, lifecycle governance expectations apply: defined intended use, documented validation, ongoing monitoring, & controlled change management.[3–7]



AI-Enabled Manufacturing and Quality

Manufacturing:

AI-enabled monitoring (soft sensors, multivariate analytics) improves detection of drift and process instability.[10,11] Digital twins are typically deployed first as advisory models, then evolve toward integrated, model-informed decision support and control.[12,13] As model influence increases, systems must support validated deployment, continuous monitoring, and controlled change management across both site and networked environments.

Quality / RTRT:

AI enables model-informed real-time release decisions when supported by validated data and process knowledge.[3,4,7,10]

Digital twins provide the predictive foundation for model-informed monitoring and RTRT decisioning

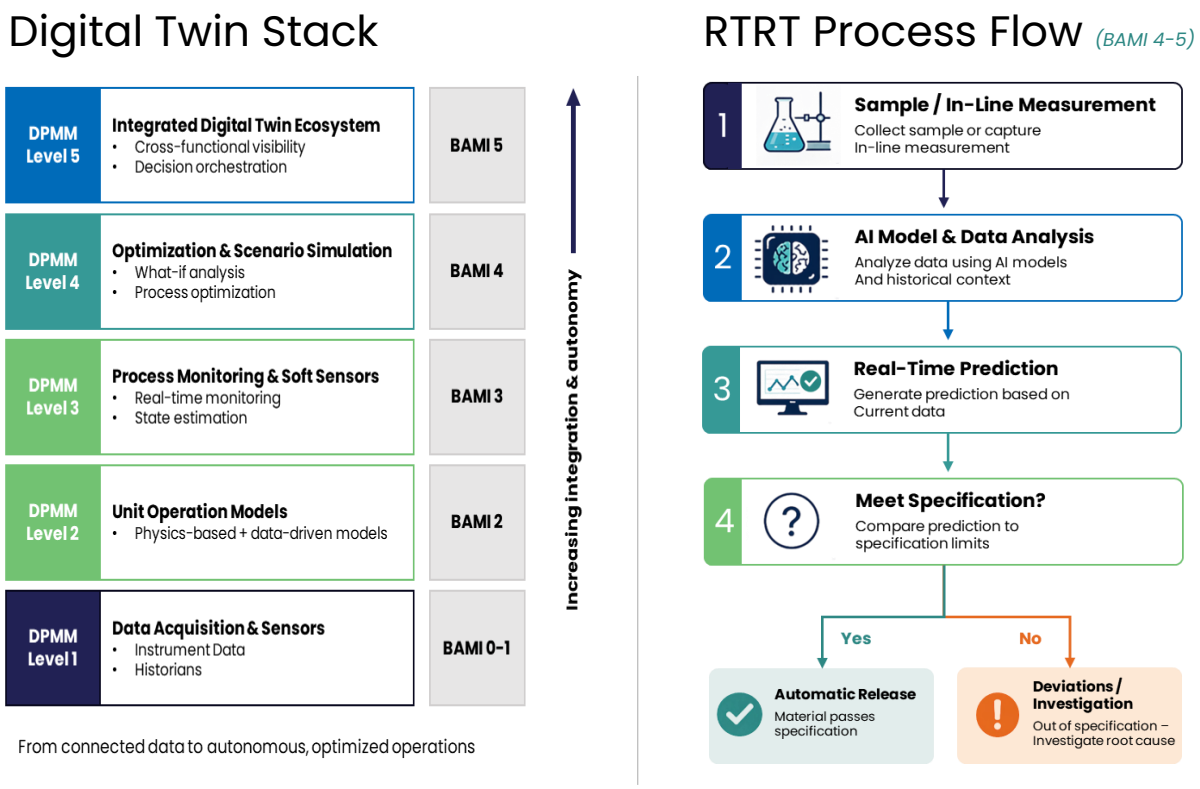


Figure 8. Digital twin–enabled monitoring and RTRT architecture.

Sensor and process data feed monitoring models and digital twins, enabling simulation, prediction, and progression from advisory insights to model-informed release decisions.

CDMO Archetypes in an AI-Enabled Ecosystem

CDMOs can pursue distinct AI-enabled operating models:

01 **Internal Optimization:**
Internal MVDA and monitoring to improve execution; outputs shared as insights.[10,11]

02 **Collaborative Development:**
Co owns models and artifacts with sponsors; DISCO style agreements define data/model governance across organizations.[9]

03 **Networked Intelligence:**
Standardized interfaces for model deployment/monitoring; participation in federated learning or cross site model reuse under robust governance.[12,13]

Over time, competitive advantage will shift toward CDMOs capable of operating within networked intelligence models, where data, models, and process knowledge are treated as governed, reusable assets.

Sponsors should align CDMO selection and contracting to the operating model required by the product and the organization's maturity and governance posture.[1,9]

Category	Internal Optimization	Collaborative Development	Networked Intelligence
AI Capability	Internal MVDA & Monitoring	Joint Model Development	Federated Learning & Model Sharing
Data Ownership	Internal Data Only	Shared Data & IP	Local Data, Federated Access
Governance	Internal Controls	Joint Governance	Standard Interfaces & Policies
Collaboration Model	Insight Sharing	Structured Co-Development (DISCO)	Cross-Site Model Reuse
Use Cases	Process Performance Optimization	Model-informed Development & Tech Transfer	Network-wide Learning & Adaptive Optimization

Workforce Constraint Spans Overall

Figure 9. CDMO operating models for AI-enabled biologics manufacturing.
Archetypal CDMO roles and their implications for data sharing, model governance, and sponsor collaboration.

Why AI Stalls in Biologics Manufacturing

AI initiatives stall for structural reasons:

01 **Digital fragmentation:**
incomplete integration between OT systems, MES, LIMS, historians, and enterprise layers limits data fitness and model portability.[8]

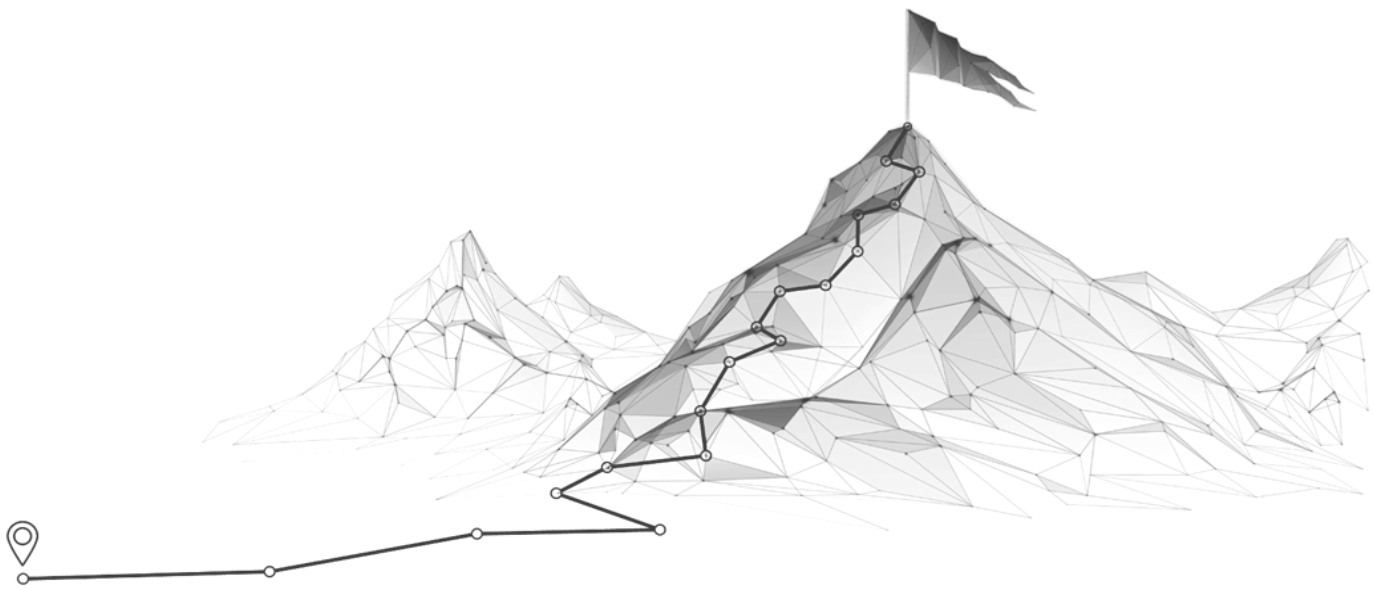
02 **Vendor lock in and interoperability gaps:**
proprietary formats and interfaces increase effort to deploy models consistently across sites.[8,10]

03 **Governance gaps:**
many organizations implement AI before mature governance, risking non-compliance or rework when models influence regulated decisions.[2,6,7]

04 **Skills and ownership:**
unclear responsibility for model lifecycle and insufficient cross functional capability slows progress.[14,15,17]

05 **Misaligned incentives:**
sponsor–CDMO contracting often treats data/models as by products, limiting incentives to invest in reusable analytics.[1,9]

AI doesn't fail on capability it fails on coordination across systems, organizations, and incentives.

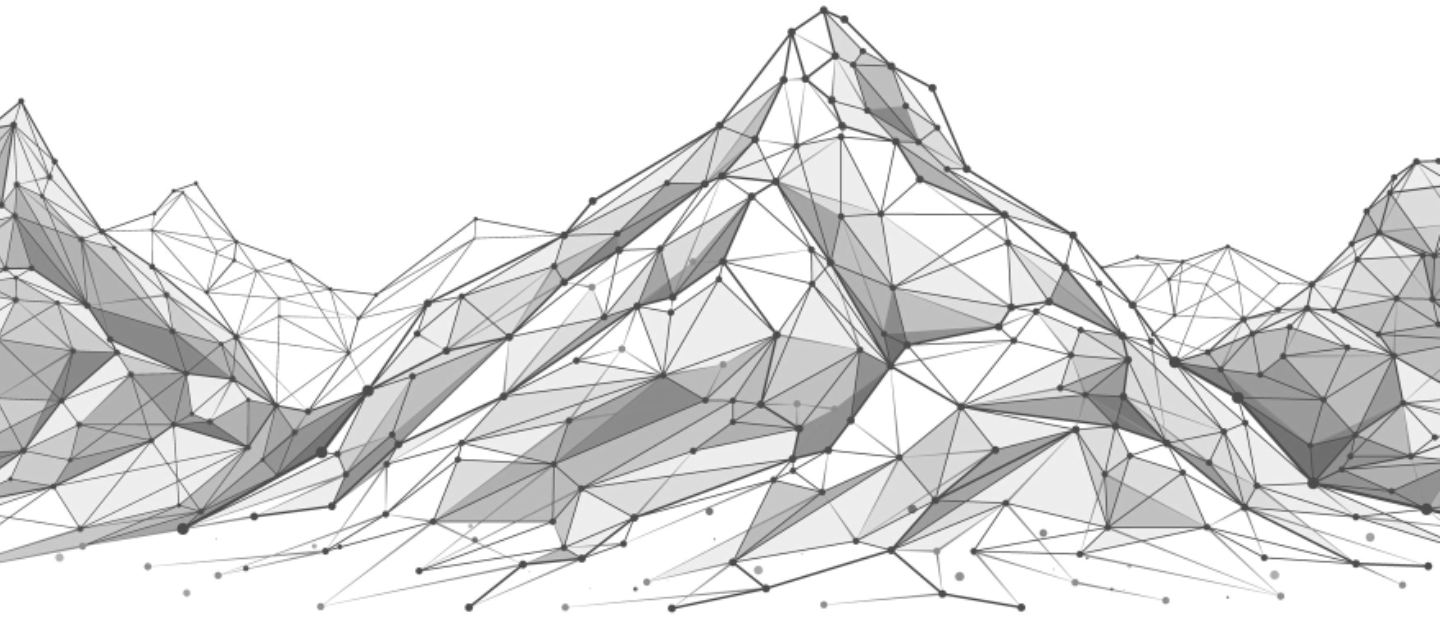


Skills, Workforce, and Organizational Design

Workforce studies focused on bioprocessing and Industry/Biopharma 4.0 highlight concrete skills gaps. The gap is especially apparent in automation, data, and analytics. It is critical to provide methods to identify and plan for future skills needs.[14] ISPE's Pharma 4.0 workforce framework reinforces the need for structured skill management, governance, and targeted upskilling to support digital and AI driven operations.[15]

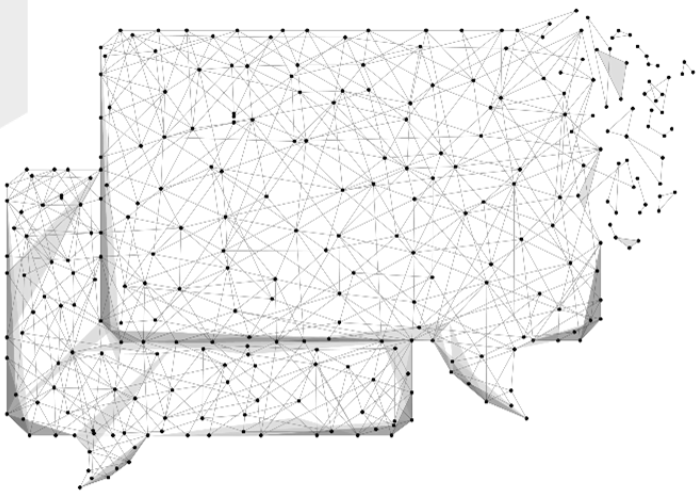
A practical organizational pattern is a cross functional AI operating model that spans process engineering, IT/OT, data science, and QA, with clear ownership of model development, validation, deployment, monitoring, and change control aligned to GAMP AI lifecycle expectations.[7,15] This operating model increasingly depends on shared systems that enforce governance, track model lineage, and coordinate deployment across functions and organizations.

At a national and ecosystem level, policy documents emphasize that scaling biotechnology and biomanufacturing will require expanded, equitable training pathways and broader workforce development programs, reinforcing that the talent constraint is systemic.[17]



Part IV – **Outlook**

Predictions and actions for **2026–2029**



This section summarizes expected developments across regulation, digital twins, CDMO offerings, federated learning, and organizational capability and translates them into near term actions.[3–7,10–13,14–17]

2026–2029 Predictions

1. **AI specific GMP expectations will crystallize.** Draft Annex 22 is likely to be finalized and inspection experience will shape practical expectations for documentation, monitoring, and lifecycle controls, with GAMP AI providing implementation discipline.[6,7]

2. **DPMM + BAMI will become standard readiness framing.** Leading sponsors and CDMOs will assess plants and partnerships with plant maturity (DPMM), integration maturity (DISCO), and AI maturity overlays to prioritize investment and outsourcing decisions.[1,8,9]

3. **Digital twins will become standard in new or upgraded facilities.** Digital twins of key unit operations will increasingly be included in facility design and operational strategies, especially among advanced CDMOs.[10,12,13]

4. **CDMOs will productize "AI ready" services.** Offerings will increasingly include harmonized data standards, model hosting, digital twins, and governance aligned delivery models in contracts.[1,9,13]

5. **Federated approaches will dominate cross company learning,** becoming the default architecture for AI-enabled biomanufacturing due to structural constraints on data centralization.[12,13]

6. **Workforce and operating models will be the binding constraint.** Organizations with structured skill management and clear lifecycle ownership will outpace peers.[2,14,15,17]

7. **AI heavy filings and inspections will increase.** By the late 2020s, submissions and inspections will more frequently address AI enabled control strategies and lifecycle governance explicitly.[3,4,6,7]

Figure 10. Expected maturation of AI-enabled manufacturing practices in biopharma (2026–2029+)

Timeline showing how regulatory expectations, operational frameworks, digital twins, CDMO service models, federated learning approaches, workforce constraints, and AI-related regulatory interactions are likely to evolve and mature across the late 2020s.

What to Do Now

01 **Anchor AI in economics.**
Define where AI can materially impact yield, robustness, tech transfer time, deviation rates, or release lead time.[1,10]

02 **Assess readiness with DPMM, BAMI, and DISCO.**
Baseline plant digital maturity (DPMM), cross organization integration maturity (DISCO), and AI maturity (BAMI) to prioritize sites and partnerships.[8,9]

03 **Align governance with emerging standards.**
Update policies and SOPs to reflect EMA, EFPIA, FDA guidance, draft Annex 22, and GAMP AI lifecycle expectations (validation, monitoring, change control).[3–7]

04 **Run focused, governed pilots.**
Select 1-2 feasible, high value use cases (e.g., soft sensors in a critical unit operation; model assisted tech transfer) and implement end to end with documented intended use, validation, monitoring, and change management.[7,10–12]

05 **Invest in skills and contracts.**
Build a skills roadmap (automation/data/analytics/GxP AI) and revisit sponsor–CDMO agreements so data and models are treated as governed assets with clear ownership, access, and responsibilities.[9,14,15,17]

06 **Evaluate enabling infrastructure**
Identify whether current systems can support model lifecycle management, cross-site deployment, and governed data exchange, or whether new architectural approaches are required.

From Framework to Implementation

About Axio BioPharma:

Axio BioPharma is focused on building the infrastructure required to scale AI in biologics manufacturing.

Its work centers on the boundary between process development, manufacturing, and data systems, where most AI initiatives fail to scale. Rather than treating AI as a standalone capability, Axio approaches it as a system that must operate across sites, organizations, and regulatory environments.

This perspective underpins both the frameworks introduced in this report and the development of federated, model-driven systems.

A coordination layer for federated systems

AI in biomanufacturing requires:

- Cross-site learning without centralizing raw data
- Reuse of process knowledge across development and manufacturing
- Governance of model lifecycle in regulated environments

This defines a new architectural layer, one that operates across organizations rather than within a single system

Introducing Lattice:

Lattice is Axio's system in development for enabling federated, model-driven biologics manufacturing.

It is being developed to coordinate existing systems and data environments, allowing organizations to learn across sites while maintaining control over sensitive data.

What this enables

- Model lifecycle management across development and manufacturing
- Reusable process intelligence (models, features, process definitions)
- Cross-site comparison and continuous learning
- Alignment with emerging GxP expectations

Lattice represents the type of infrastructure required to move from fragmented AI initiatives (**BAMI 1–3**) to scalable, networked systems (**BAMI 4–5**).

Axio is engaging a small set of partners to co-develop and validate this approach across real-world programs.

Appendix A – References

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Appendix B – Glossary of Key Terms

Biomanufacturing AI Maturity Index (BAMI)
A six level model (0–5) describing AI readiness and capability in biologics manufacturing, focusing on data fitness, model lifecycle governance, tech transfer portability, operations integration, and regulatory/inspection readiness.[7–9]

Digital Plant Maturity Model (DPMM)
A BioPhorum framework describing five levels of plant digital maturity, from paper based operations to fully automated, self optimizing plants integrated into value chains.[8]

DISCO (Digital Integration of Sponsor and Contract Organizations)
A BioPhorum playbook for structuring sponsor–CDMO digital collaboration, including digital collaboration agreements, defined data flows, and phased implementation pathways.[9]

Digital Twin
A digital representation of a process, asset, or system used to simulate, analyze, and optimize performance; in biopharmaceutical contexts, often applied to unit operations and integrated with PAT and process understanding.[12,13]

Federated Learning
A model development approach in which training data remains local and only model updates, parameters, or representations are shared supporting cross site learning while reducing centralized data exposure.[12,13]

GAMP® Guide: Artificial Intelligence (GAMP AI)
An ISPE guide describing how to develop, validate, deploy, and manage AI enabled computerized systems in GxP environments, emphasizing lifecycle controls, risk based approaches, and safeguarding patient safety, product quality, and data integrity.[7]

EU GMP Annex 22 (Draft): Artificial Intelligence
A draft EU GMP annex proposing expectations for AI systems used in GMP, including documentation, monitoring, and risk based controls; intended to complement existing EU GMP requirements such as computerized systems and documentation expectations.[6]

Reflection Paper (EMA) on AI in the Medicinal Product Lifecycle
EMA's framework describing considerations for AI/ML across the medicinal product lifecycle, including manufacturing, emphasizing risk based approaches, data quality, transparency, and oversight.[4]

Real Time Release Testing (RTRT)
A release strategy where product quality is assured through process understanding and in /on line measurements, potentially reducing reliance on end product testing; AI may contribute when appropriately validated and governed.[3,7]

Soft Sensor
A model (often multivariate) that estimates a process variable or attribute that is difficult/slow to measure directly, using other available measurements; common in advanced monitoring strategies.[10,11]

Process as Code
A structured, machine readable representation of a process and its control strategy (and associated digital artifacts), intended to improve portability and consistency during tech transfer and scale up. (Conceptual framework used in this report.)

Pharma 4.0 / Biopharma 4.0
A set of approaches applying digitalization, automation, data integration, and advanced analytics/AI to pharmaceutical/biopharmaceutical development and manufacturing, including workforce and operating model implications.[10,14,15]